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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,226

05/06/2005

Carsten Horn

0003.04

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06/18/2009

USDA-ARS-OFFICE OF TECHNOLOGY TRANSFER  
NATIONAL CTR FOR AGRICULTURAL UTILIZATION RESEARCH  
1815 N. UNIVERSITY STREET  
PEORIA, IL 61604

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

06/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,226	<b>Applicant(s)</b> HORN ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 23, 25-34 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-22, 24, 35-46 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/11/2009 has been entered.

Claims 1-48 are pending. Claims 1-10,23,25-34 and 47 are withdrawn. Claims 11-22,24,35-46 and 48 are under examination in the instant office action.

Claims 35-46 and 48 are examined only to the extent that they read on the elected invention, specifically methods involving invertebrates. *Thus, the examined subject matter of claims 35-46 and 48 is the same as that of claims 11-22 and 24.* Claims should be limited to the elected subject matter prior to allowance of the elected invention.

### ***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11-22,24, 35-46 and 48 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full breadth of the claims is withdrawn in light of Applicant's amendments to the claims.

Claims 21 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21 and 45 are highly unclear as set forth below. For this reason, they appear to not be enabled. Given the structural limitations set forth in the independent claims, it is not clear where placement of a promoter in the first cassette would result in operable linkage upon FLP-mediated exchange as placement of the promoter within the FLP sites of the first cassette would result in loss of the promoter upon exchange. Placement of the promoter outside the FRT sites of the first cassette would result in removal of the promoter upon pairing and excision of the flanking and internal halves. Applicant is requested to clarify the placement of the promoter. It appears, perhaps, language limiting the promoter to outside the flanking FRTs but not between the flanking and internal halves that will excise is required.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 45 remain rejected and claims 1-20,22,24, 35-44,46 and 48 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 45 remain unclear because, as amended, it is not clear if the operable promoter of line 4 is the same as that now recited in line 2. Claims 21 and 45 have been amended. However, “said operable promoter” in line 3 lacks antecedent basis. The placement of the promoter in the cassettes is unclear as is the resulting effect. The term “a coding region” is unclear as well as a coding region is not required of the second cassette.

Claims 1-22,24, 35-46 and 48 are highly unclear. Applicant is referred to the language set forth at the paragraph bridging pages 2-3 of the office action dated 03/19/2008 for general clarification. Some language issues can be resolved by inclusion of a functional limitation that implies to one of skill in the art, the necessary structural limitations as set forth in the specification. More specifically, the language

Art Unit: 1632

used to establish the patter of FRT sites in the cassettes is cumbersome and perhaps unnecessary, see for example lines 5-7 of claim 11. At line 10, “exchanging....by a site-specific recombinase” is unclear.

"Exchanging...by" requires use of a verb. The term “by” is confusing. Use of the terms “at one end” and “at an other end” are also unclear. The claims should more precisely indicate the position of elements.

Claims 11 and 35 fail to relate back to the preamble in a positive process to indicate that any targeting of a heritable integration of a transgene is achieved.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/  
Primary Examiner, Art Unit 1632